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January 13, 2003

First Class Mail

Examiner M. P. Allen, Art Unit 1631
United States Patent and Trademark Office
Washington, DC 20231

Re: **Systems and Methods for Characterizing a Biological Condition or Agent Using
Calibrated Gene Expression Profiles**

Application No.: 09/821,850
Date Filed: 03/29/2001
Our File: 2331/112

Dear Examiner Allen:

In response to the Office Action of December 24, 2002 stating that the USPTO has no record of an IDS filed for the above-referenced matter prior to May 29, 2001 (see Office Action, p.2 attached), I enclose a duplicate copy of the Information Disclosure Statement dated May 10, 2001 and also a copy of the return post card which was date stamped received by the United States Patent and Trademark Office on May 14, 2001.

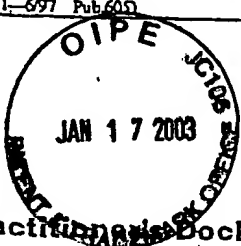
Please do not hesitate to contact me with any further questions you might have regarding this matter.

Sincerely,

Barbara J. Carter, Ph.D.

BJC/cph

Enclosure/234169



#18

Practitioner's Docket No. 2331/112

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

Patent application

of

Inventor(s)

for

Title of invention

JAN 21 2003

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the specification of which is being transmitted herewith

OR

In re application of: Bevilacqua, M. et al.

Serial No.: 09 / 821,850

Group No.:

Filed: March 29, 2001

Examiner:

For: Systems and Methods for Characterizing a Biological Condition or Agent Using Precision Gene Expression Profiles

Commissioner for Patents

Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231
37 C.F.R. 1.8(a)

☒ with sufficient postage as first class mail. ☐ as "Express Mail Post Office to Addressee" 37 C.F.R. 1.10

Mailing Label No. _____ (mandatory.)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Harriet Strimpel

Date: May 10, 2001

Harriet M. Strimpel

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by Express Mail must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Information Disclosure Statement [6-1]—page 1 of 7)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last."

37 C.F.R. 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORM PTO-1449 (PTO/SB/08A and 086)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections

, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

(Information Disclosure Statement [6-1]—page 2 of 7)

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.